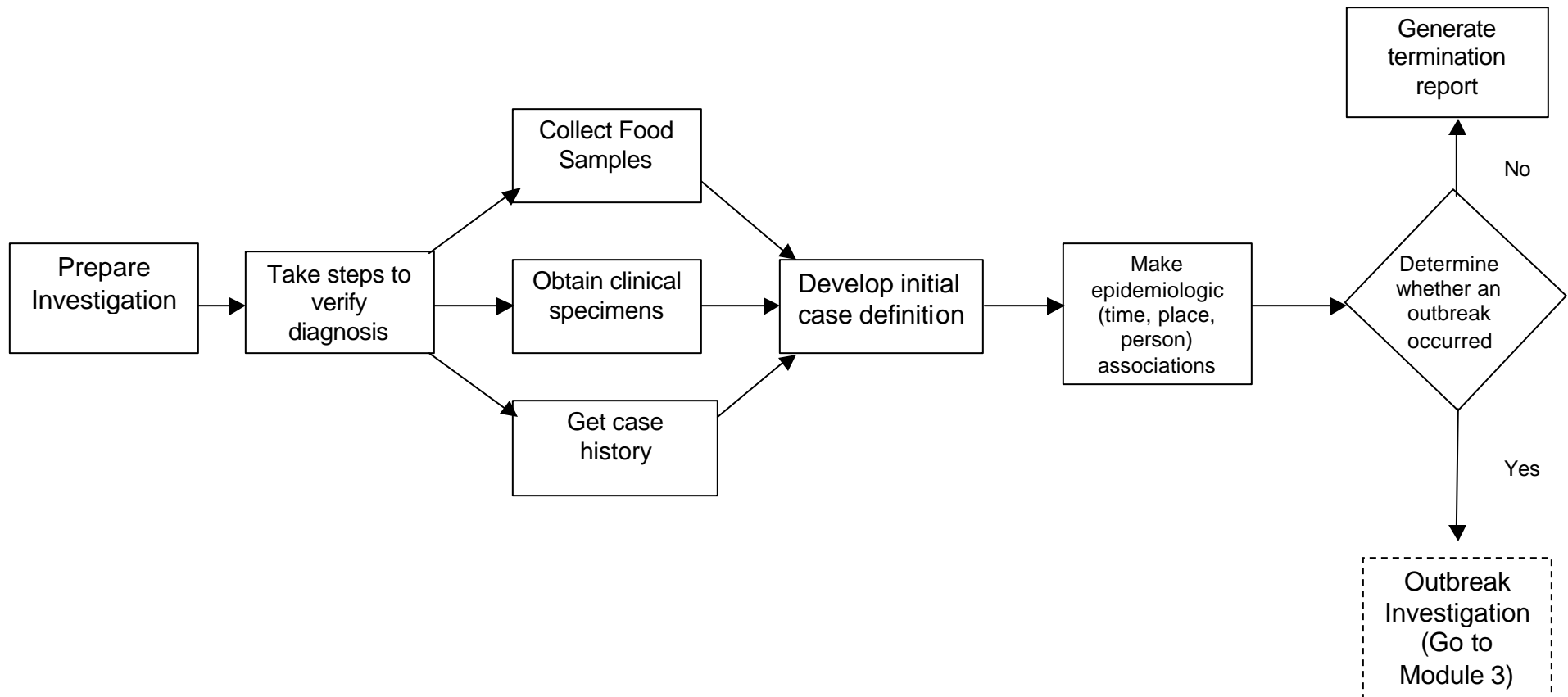


## MODULE 2: OUTBREAK DETERMINATION



## **I. Task List**

### **A. Prepare Investigation**

- ☐ Identify outbreak investigation team leaders, members and responsibilities.
- ☐ Share surveillance information with team members and other designated staff.
- ☐ Get appropriate approval from supervisors for planned activities.
- ☐ Gather supplies and equipment needed to carry out case finding.
- ☐ Review scientific information regarding known or suspected agents.
- ☐ Notify state agencies and local health departments that may be impacted.

### **B. Take Steps to Verify Diagnosis**

- ☐ Review preliminary information to verify accuracy.
- ☐ Identify what further laboratory analysis or information gathering is needed.
- ☐ Refer to appropriate health care provider or agency with jurisdictional authority.

### **C. Get Case Histories – see Appendix 15, Interviewing**

- ☐ Establish rapport with the individuals being interviewed.
- ☐ Determine if food samples or clinical specimens are available for testing.
- ☐ Identify who will collect the samples.
- ☐ Fully complete all forms.
- ☐ Ask if individuals have unanswered questions or additional information to share.
- ☐ Thank them for their cooperation.

### **D. Collect Food Samples**

- ☐ Take steps to ensure samples are not lost or destroyed.
- ☐ Collect samples using aseptic technique.
- ☐ Hold samples under conditions that maximize usefulness.
- ☐ Determine which tests to request through consultation with laboratory staff.
- ☐ Complete forms.

**E. Obtain Clinical Specimens**

- ❑ Ask if the individual is experiencing symptoms or has submitted a stool specimen.
- ❑ Collect specimens following guidance provided by the MDCH laboratory.
- ❑ Determine which tests to request.
- ❑ Complete the MDCH or regional lab form - required for each specimen.
- ❑ Contact laboratory staff to arrange for testing before sending samples.

**F. Develop an Initial Case Definition**

- ❑ Develop initial case definitions to be used to determine if an individual is an outbreak-associated case.
- ❑ Classify cases in categories based on the certainty of diagnosis.  
(*Definite/Confirmed, Probable/Presumptive, Possible/Suspect*)
- ❑ Revise and make definitions more specific as new information is received.

**G. Make Epidemiologic Associations (Person, Place, Time)**

- ❑ Organize key information from cases using a line list or similar document.
- ❑ Summarize data by person, place and time.
- ❑ Systematically review all information and develop initial hypothesis.

**H. Determine Whether an Outbreak Occurred**

- ❑ Review definitions of a foodborne illness outbreak.
- ❑ Review EH and CD logs for potentially associated cases.
- ❑ Designated LHD staff should determine if an outbreak has occurred.
- ❑ If an outbreak has not occurred, document your conclusions - "Termination report".
- ❑ Document why a final report was not written.
- ❑ If a foodborne illness outbreak has occurred, proceed to Module 3, Outbreak Investigation.

## II. Notes

### About This Module

The agent(s) causing foodborne outbreaks frequently go undiagnosed or are misdiagnosed. To determine if an outbreak is occurring investigators must often:

1. Verify (or establish) the diagnosis, and
2. Actively look for additional cases (active case finding).
  - If the etiologic agent has been laboratory *confirmed*, at-risk individuals can be identified using existing information about how that agent is transmitted.
  - If the cause is *unconfirmed*, at-risk individuals can include individuals who attended the same events as ill persons or who also ate suspect foods.
  - Active case finding may be initiated before an outbreak has been confirmed and should continue throughout an outbreak investigation.
3. Determine if cases are associated (person, place or time).

#### Example 1:

Two unrelated persons, with unconfirmed illness, report that they became ill after eating sandwiches purchased at a weekend festival. Active case finding activities could include:

- 1) Review of the food-related alert/complaint surveillance log or the reportable communicable disease log for other reports linked with the same event or with similar foods in the food history.
- 2) Attempt to interview persons who managed or attended the event.

Contact area hospital emergency room or infection control coordinators to assess if there has been an increased number of persons reporting with similar signs and symptoms.

**Example 2:**

An unexpected increase in the level of reported *Shigella sonnei* infections over a three-week period is detected in your county. Active case finding activities could include:

- 1) Interview known cases to determine any common associations (person, place, or time) and assess the risk for ongoing disease transmission.
- 2) Develop and distribute a health advisory to local health-care providers regarding the signs/symptoms of *Shigella sonnei* infections, how to collect and submit appropriate specimens and a reminder about reporting requirements.
- 3) Interview contacts of cases to determine if there are others experiencing symptoms that have not sought medical care.

### III. Task List Related Information

#### A. Prepare Investigation

- ❑ Identify outbreak investigation team leaders, members and responsibilities. LHDs should have written procedures that identify:
  - Investigation team leader(s)
  - Chain-of-command
  - Who is the contact for sharing information (e.g., media relations and requests, concerned citizens, state and federal agencies)
- ❑ Share surveillance information with team members and other designated staff.
  - Regularly scheduled group meetings save time and give everyone the same information at the same time.
  - Notify key LHD staff of planned actions.
  - Allow staff to organize the collection of case histories and samples.
  - Coordinate with laboratory for testing of clinical specimens and/or food samples.
- ❑ Get appropriate approval from supervisors for planned activities
  - Home/restaurant visits,
  - Interviews, and
  - Travel assignments.
- ❑ Gather supplies and equipment needed to carry out case finding:
  - Required forms
  - Specimen collection/transport materials
  - Foodborne Illness Investigation Kit
- ❑ Review scientific information regarding known or suspected agents. Published scientific information can provide:
  - Known modes of transmission
  - Infective dose

- Susceptible populations
  - Incubation period
  - Known reservoirs
  - Period of communicability
  - Recommended control measures
- ❑ Notify state agencies and local health departments that may be impacted.
- It is required to report to both MDA and MDCH.
  - Multiple agencies at the state and federal levels may be involved depending on where the food was prepared or served and the residence of the affected individuals.
  - Verify which state agencies have jurisdictional authority (as needed).
  - Coordinate activities or request assistance (as needed).

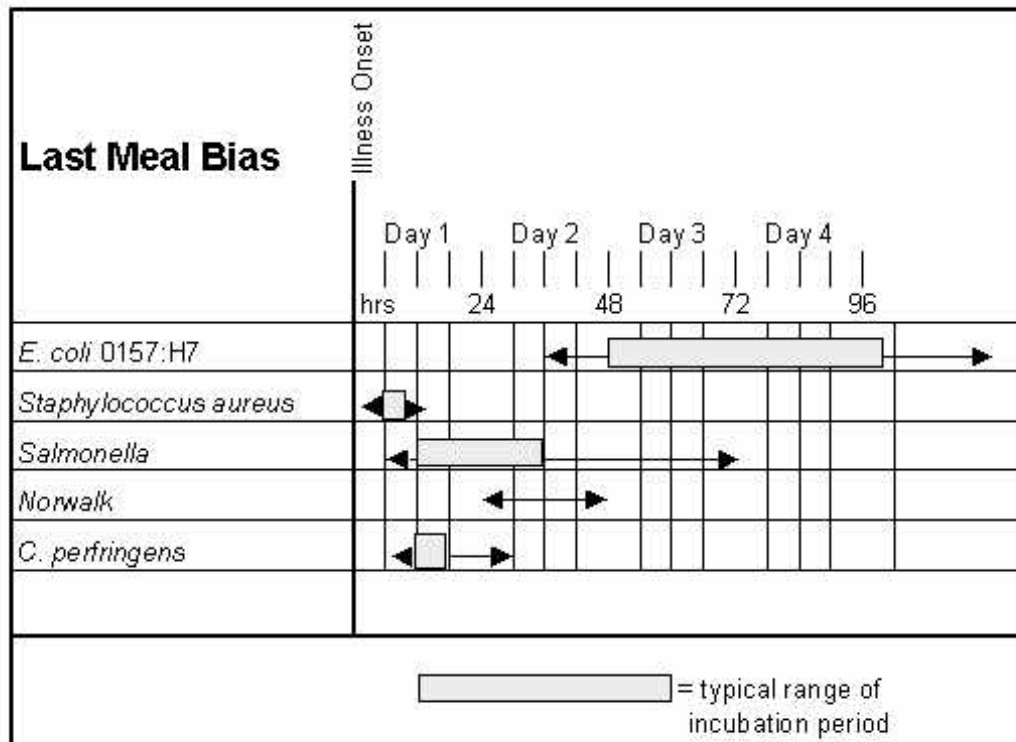
## **B. Take Steps to Verify Diagnosis**

- ❑ Review preliminary information to verify accuracy.
- Thorough case history gathered?
  - Appropriate clinical and food samples have been collected?
  - Appropriate laboratory tests have been performed?
- ❑ Identify what further laboratory analysis or information gathering is needed.
- Identifying the agent is a top priority. Causative agents are laboratory confirmed in few foodborne-illness outbreaks.
  - Early collaboration by laboratory, communicable disease, and regulatory staff reduces repeat contacts with affected individuals.
- ❑ Refer to appropriate health care provider or agency with jurisdictional authority.

## **C. Get Case Histories – see Appendix 15, Interviewing**

- ❑ Establish rapport with the individuals being interviewed.
  - Inform individuals up front that multiple contacts may be necessary.
  - Remind individuals that cooperation is needed to identify cause(s) of their illness and prevent others from becoming ill.
  - Interviewing skills are essential for a successful investigation – see Module 3, Epidemiological Investigation Section for more details.
  - Refer questions regarding medical care to a nurse or health-care provider.
  - Obtain information about disease causing organisms from current text – see references.
- ❑ Determine if food samples or clinical specimens are available for testing.
  - Ask if still sick.
- ❑ Identify who will collect the samples.
- ❑ Fully complete all forms.
  - Different forms are used by various disciplines at present.
    - Routine unconfirmed illnesses: complete IAMFES Form C 1 and 2
      - Recommended for use by Environmental Health.
    - Routine laboratory confirmed infections: MDCH Enteric Illness Report.
      - Required for use by communicable disease staff to report to MDCH.
    - Gather a complete 72 hour meal history
    - Remember great potential for “last meal bias” – blame illness on last food eaten.
      - Typical incubation periods for many foodborne agents are > 12 hours
      - Foods eaten during any one of several meals could be the real culprit





- Tabulating information on a line list is a standard procedure that efficiently identifies risk factors (e.g., attendance of special event).
    - The format of IAMFES Forms D 1and D2, Case Histories Summary, is recommended.
    - See Section G. Make epidemiological associations for more information.
  - Use of same forms throughout the entire investigation increases consistency.
    - Transfer information between forms as needed to minimize re-interviewing.
  - If a customized form is needed:
    - Consider modifying a generic foodborne illness questionnaire. See Module 3, Epidemiological Investigation Section.
    - Consult an epidemiologist or experienced investigator to ensure questions are unbiased.
- Ask if individuals have unanswered questions or additional information to share.
- Thank them for their cooperation.

#### **D. Collect Food Samples**

- ❑ Take steps to ensure samples are not lost or destroyed.
  - Collect food samples early to prevent loss and to protect sample integrity.
    - Restaurants and retail stores
      - Take possession of samples
      - Check garbage/dumpster
    - Client Homes
      - Make arrangements for clients to hold samples pending investigation.
      - Provide instructions for proper storage until pick up or delivery.
  - IAMFES Form F is recommended to record condition of the sample.
- ❑ Collect samples using aseptic technique.
  - Amount recommended is 50-100 gm. or 4 oz.
- ❑ Hold samples under conditions that maximize usefulness.
  - Maintain identity – keep original packaging and labels of a processed food. Key information includes:
    - lot numbers,
    - expiration dates,
    - use-by dates, and
    - processor information.
  - Use sealed container or double bag to minimize potential for cross contamination.
- ❑ Determine which tests to request through consultation with laboratory staff.
  - Submit only those samples implicated by an investigation.

- Food samples from isolated complaints of foodborne illness are not routinely tested.
  - Exceptions are made on case-by-case basis for severe illnesses (e.g., listeriosis, botulism, *E. coli* O157:H7).
- Local health department staff decides tests (consistent with MDCH Laboratory guidance).
- MDCH Laboratory guidance takes precedence over information contained in IAMFES.
- IAMFES contains several tables that summarize key information about the pathogens known to be associated with specific foods.

### Example 3: Food Sampling

An initial complaint is received at the local health department that six people, from three households, experienced nausea, vomiting and some diarrhea last night. Symptoms began 2-4 hours after consuming foods from a dinner buffet.

1. Sanitarians visited the restaurant to inspect the facility and collect samples of foods consumed by complainants that were still on hand.
  - Samples of 10 foods eaten by these persons were collected.
2. Samples of all foods were held until one or more foods were linked with illness (a hypothesis was developed regarding the cause of the outbreak).
  - A case control study implicated two of the ten foods.
3. Local health department staff reviewed references and consulted with laboratory staff prior to deciding which tests to request. Given symptoms and incubation period staphylococcal intoxication was suspected. See Control of Communicable Diseases Manual (pp. 203-206) or IAMFES Table B. (p.102).
4. Laboratory staff were contacted to make arrangements for receipt and testing of the samples.
  - Samples of the two implicated foods were tested for *Staphylococcus aureus* and enterotoxin.

#### □ Complete forms.

- The MDCH Microbiology/Virology Test Requisition (DCH-0583) is required for each specimen.

## E. Obtain Clinical Specimens

- ❑ Ask if the individual is experiencing symptoms or has submitted a stool specimen.
  - Refer to communicable disease staff, individuals who submitted specimens but results are unknown.
  - Consult an epidemiologist before asking asymptomatic individuals to submit specimens.
- ❑ Collect specimens following guidance provided by the MDCH laboratory.
  - Same considerations as with food samples (see above).
  - Do not submit samples of vomitus.
  - Coordinate transportation and delivery of samples with MDCH laboratory staff.
    - Ensure there is staff available to receive samples.
- ❑ Determine which tests to request.
  - Choose specimens that are appropriate to the signs and symptoms reported.
- ❑ Complete the MDCH or regional lab form required for each specimen.
  - Samples should be submitted to the laboratory properly labeled.
  - MDCH Microbiology/Virology Test Requisition Form DCH-0583 or Regional Lab form DCH 0567 is required.
  - IAMFES Form E is optional.
- ❑ Contact laboratory staff to arrange for testing before sending samples.

### **F. Develop an Initial Case Definition**

- ❑ Develop initial case definitions to determine outbreak-associated cases.
  - A case definition is a standard set of criteria for deciding whether an individual should be classified as having the health condition of interest.
  - Differentiating primary from secondary cases is important.
    - Primary case - became infected directly from contact with the outbreak source

- Secondary case - became infected from contact with a primary case (outbreak associated) or from a food or object contaminated by a primary case.
- A case definition typically includes:
  - Signs and symptoms.
  - Demographic information
    - Person (e.g., age, sex)
    - Place (e.g., event, geographic area)
    - Time (e.g., time period of increased number of cases reported)
- Case definitions must be applied consistently to all persons under investigation.
- Classify cases in categories based on the certainty of diagnosis (*Definite/Confirmed, Probable/Presumptive, Possible/Suspect*)
  - *Definite/Confirmed*: Laboratory confirmed.
  - *Probable/Presumptive*: Typical clinical features of the disease without definitive laboratory confirmation.
  - *Possible/Suspect*: Fewer of the typical clinical features of the disease with no laboratory confirmation.
- Revise and make definitions more specific as new information is received.
  - Initial case definitions tend to be nonspecific when limited information is available.
  - Revising is an ongoing process.
  - Precise definitions reduce risk of miss-classifying cases and non-cases.

**Example 4: Outbreak Associated Cases vs. Normal Background Level**

1. Disease surveillance data is used to determine the expected number of cases (background level) for various enteric illnesses during each month.
2. Many agents that cause symptoms compatible with foodborne illness are also spread by other means. The Centers for Disease Control and Prevention recently estimated 36%, of acute gastroenteritis caused by known pathogens, was foodborne.
3. If a foodborne illness outbreak occurs, use of accurate case definitions can help identify which cases are part of the outbreak and which are part of the normal background level within the jurisdiction.

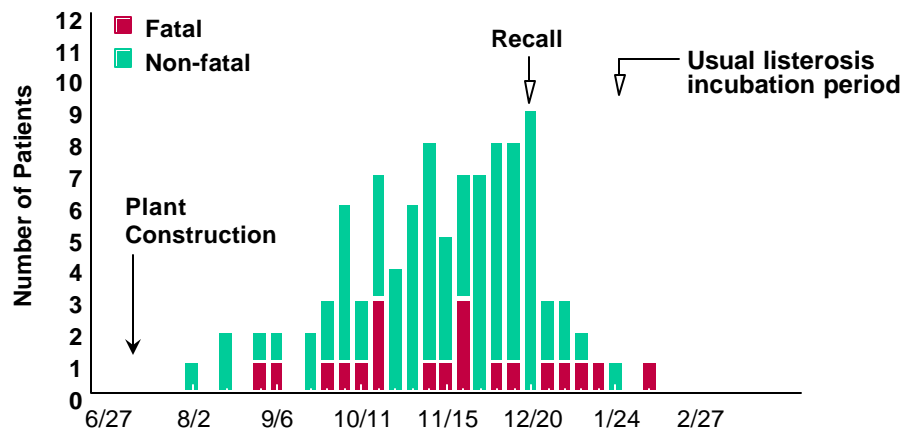
**G. Make Epidemiologic Associations (Person, Place, Time)**

- Organize key information from cases using a line list or similar document.
  - Information typically included:
    - Demographic information of cases
    - Clinical information (i.e., illness onset, signs, symptoms)
    - Food history, and
    - Laboratory results
  - Make line listing by:
    - Hand using the IAMFES Forms D1-2, or
    - Using a computer software program.
- Summarize data by person, place and time (descriptive epidemiology).
  - Summaries of descriptive epidemiologic information can help to:
    - Identify specific populations at risk of illness , and
    - Provide initial clues for the development of hypotheses.

- Commonly used methods of summarizing descriptive epidemiological information include:
  - Time - usually depicted using an epidemic curve

### Example 5: Epidemic Curve

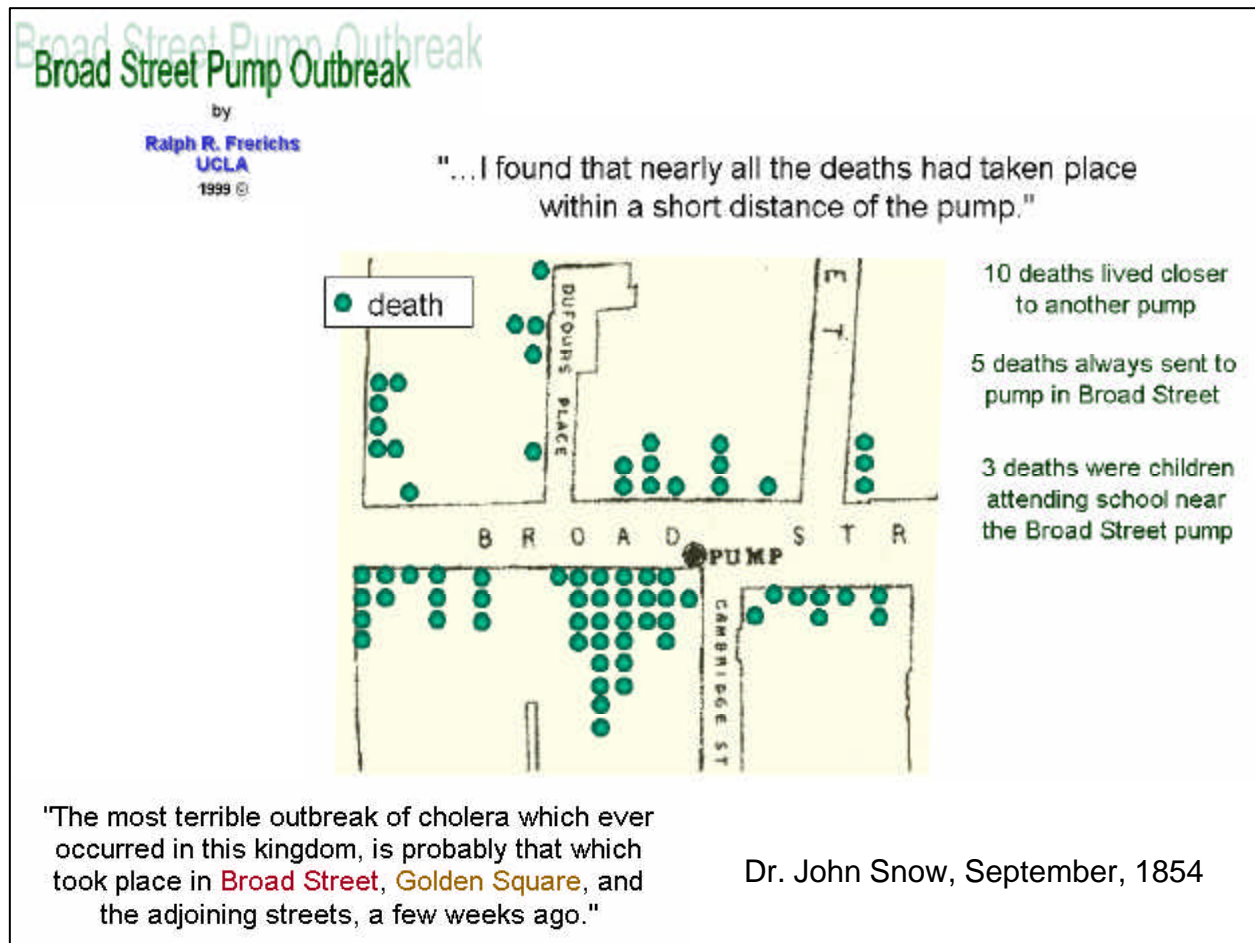
## Multistate Outbreak of Listeriosis, United States, 1998-1999



Source: Centers for Disease Control

- Key information conveyed by epidemic curves:
  - Magnitude of outbreak,
  - Time course (range of onset dates),
  - Incubation period (if time of exposure is known), and
  - Type of transmission pattern that is occurring (point source vs. sporadic vs. propagated).
- Place - a spot map is often useful for identifying geographic patterns.

### Example 6: Geographic Map



Spot maps can identify clusters linked to location of work, school, residence, recreational activities or other places where foods were consumed.



- Person – cross tabulations comparing personal characteristics of ill

### Example 7: Cross Tabulation

#### 2X2 Table

Analysis of Food Item 1

ITEM1	ILL		Total
	+	-	
+	11	4	15
-	3	17	20
Total	14	21	35

#### Single Table Analysis

Odds ratio

15.58

Cornfield 95% confidence limits for OR

2.29 < OR < 130.18\*

\*May be inaccurate

	Chi-Squares	P-values
	-----	-----
Uncorrected:	12.15	0.00049015 <---
Mantel-Haenszel:	11.81	0.00059054 <---
Yates corrected:	9.84	0.00170410 <---

Cross tabulations indicate characteristics of affected and non-affected individuals (e.g. age, race, sex, medical status, occupation, use of medications) and can provide initial clues as to at-risk populations.

- Continually update descriptive summaries as new information becomes available.
- Systematically review all information gathered and develop initial hypothesis regarding potential sources of the outbreak. Hypothesis definition: "An unproved theory...tentatively accepted to explain certain facts or to provide a basis for further investigation".
  - If the causative agent is unknown, identify agent(s) potentially involved after reviewing;
    - Symptoms of affected individuals,
    - Course and severity of disease,
    - Implicated foods, and

- Methods of preparation.
- Developing hypotheses helps clarify:
  - What is known,
  - What information is missing, and
  - What additional actions are needed to gather missing information.
- Early in the investigation:
  - Hypotheses tend to be general.
  - Several hypotheses may be plausible due to lack of information to rule in or rule out.
    - Example: many foods may be initially suspected of causing an outbreak.
- Hypotheses become more specific as the investigation proceeds.
  - Additional information is used to test, refine, or eliminate.

## H. Determine Whether an Outbreak Occurred

- Review definitions of a foodborne illness outbreak.

### **Regulatory Definition – Michigan Food Law of 2000, Section 3103**

A “foodborne illness outbreak” means an incident where two or more persons, not of the same household, have ingested a common food and have a similar disease, similar symptoms, or excrete the same pathogens, and there is a time, place, or person association between these persons; where there is a single case of suspected botulism, mushroom poisoning, paralytic shellfish poisoning, or other rare disease; or where there is a case of a disease or poisoning that can be definitely related to ingestion of food.

**General Definition – Act 92 of 2000, Section 3131 (2)**

“An outbreak is an incident in which two or more persons have the same disease, have similar clinical features, or have the same pathogen-thus meeting the case definition-and there is a time, place, or person association among these persons.”

A single case of the following warrants further investigation:

- Botulism
- Mushroom poisoning
- Ciguatera or paralytic shellfish poisoning
- Other rare conditions likely to be foodborne such as *Vibrio vulnificus*

- Environmental health staff must meet legal requirements:
  - Follow-up on food complaints and all reports of alleged foodborne illness regardless of whether or not an outbreak has occurred.
  - Submit a written investigation report for all incidents meeting the regulatory definition of a foodborne illness outbreak. (See Module 4: Concluding Actions).
- ❑ Review EH and CD logs for potentially associated cases.
  - Cross check to make sure all available information is reviewed.
- ❑ Designated LHD staff should determine if an outbreak has occurred.
  - These individuals should be trained and experienced.
  - Consult MDCH or MDA as needed.
- ❑ If an outbreak has not occurred, document your conclusions - “termination report”.
- ❑ Document why a final report was not written.
  - Investigation cannot be completed because key information is unavailable (e.g., ill person(s) moved away).
  - Incidents that meet the definition, but which available evidence indicates are not foodborne.

## Module 2: Outbreak Determination

- See Appendix 3: Forms for recommended format.
- Important to document agency actions and disposition.
- If a foodborne illness outbreak has occurred, proceed to Outbreak Investigation Module (Module 3).
  - Notify appropriate local and state agencies if not already done.